DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Skeletal Dynamics, LLC
Ms. Ana Escagedo
President
8905 SW 87 Avenue, Suite 201
Miami, Florida 33176

June 27, 2017

Re: K171590
Trade/Device Name: Distal Elbow Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: May 30, 2017
Received: May 31, 2017

Dear Ms. Ana Escagedo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171590

Device Name
Distal Elbow Plating System

Indications for Use *(Describe)*
The Skeletal Dynamics Distal Elbow Plating System is intended for fixation of fractures, fusions, osteotomies and non-unions of the radius and ulna, particularly in osteopenic bone.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary of Safety and Effectiveness
Skeletal Dynamics Distal Elbow Plating System

June 22, 2017

Submitter:
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Contact: Ana M. Escagedo, Vice President
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Establishment Registration Number: 3006742481

Name and Classification:

Name	Distal Elbow Plating System
Common Name	Plate, fixation, bone
Classification	21 CFR §888.3030
Product Code	HRS, HWC
Class	Class II

Predicate Devices:
Skeletal Dynamics Distal Elbow Plating System
(K140892) DePuy Anatomic Plating System (K082300)

Description of the Device:

The Skeletal Dynamics Distal Elbow Plating System is comprised of:

- Titanium alloy plates and screws in various configurations
- Cobalt chrome polyaxial screws
- Stainless steel K-wires (for provisional fixation not for implantation)
- System specific instrumentation

The current Skeletal Dynamics Distal Elbow Plating System (K140892) includes the radial head and proximal ulna plates. Plates in double hockey stick, Y and coronoid shape configurations with the same node and inter-node features as the radial head plate are being added for use in the proximal radius and ulna in this submission. All plates are made of medical grade titanium alloy. The radial head, proximal ulna and coronoid plates are offered in left and right applications, the proximal ulna plate is provided in various lengths, and the double hockey stick and Y plates are in single size and have bilateral application. Additional screws length as well as new threaded pegs, washers, polyaxial locking screws, and instruments

have been added in the subject system in this submission. The system is provided non-sterile and is sterilized in the user facility.

Intended Use:
The Skeletal Dynamics Distal Elbow Plating System is intended for fixation of fractures, fusions, osteotomies and non-unions of the radius and ulna, particularly in osteopenic bone.

Summary of Technological Characteristics / Substantial Equivalence:
The substantial equivalence of the Skeletal Dynamics Distal Elbow Plating System to the predicate device is demonstrated by similarities in intended use, indications for use, materials, design (fundamental scientific technology), performance, sterility and packaging, and does not present any new issues of safety or effectiveness.

Performance Testing:
Engineering analysis and preclinical testing demonstrated that the Skeletal Dynamics Distal Elbow Plating System is substantially equivalent to the predicate device currently marketed. Mechanical testing which established equivalency included conformance to ASTM F382-14, Standard Specification and Test Methods for Metallic Bone Plates and ASTM F543-17, Standard Specification and Test Methods for Metallic Bone Screws.

Conclusion:
The Skeletal Dynamics Distal Elbow Plating System is substantially equivalent to the predicate devices identified in this premarket notification.